K670304

TABLE OF CONTENTS

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K070307

510(k) Summary

Date
January 25, 2007

Submitters Information
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Finland
Phone: +358 45 78822000
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Contact: Kai Lanér

Trade Name
Digora PCT or Digipod

Common Name
Imaging plate reader

Classification
Solid state x-ray imager

Predicate Device
Fuji FCR 9000HQ

510(k): K951373

Product Description
A digital radiography system for imaging plates located in cassettes. The system may be used with x-ray equipment utilizing film or similar cassettes. The image is recorded on reusable imaging plate which substitutes for conventional x-ray film. The x-ray energy absorbed in the imaging plate remains stored as a latent image. When fed to the device the stored energy is released as an optical emission proportional to the stored energy when the imaging plate is stimulated pixel by pixel by a scanning laser. An optical system collects the emission for photoelectronic system, which converts the emission to digital electronic signals. These signals are processed in a computer system which formats and stores the signals.

Further image processing, display and achieving are carried out with an auxiliary software a PC and a display.

K070364

Intended Use
The Digora PCT imaging system is indicated for capturing, digitization and processing of extraoral, maxillofacial, cephalometric and podiatric x-ray images stored in imaging plate recording media.

Technological Characteristics
The device is capable of reading imaging plates such as 15 cm x 30 cm, 18 cm x 24 cm and 24 cm x 30 cm or 8 inch x 10 inch and 10 inch x 12 inch. The image pixel bit depth is 16 bits.

Performance data
A comparison between Digora PCT or Digipod and Fuji FCR 9000HQ was made to evaluate the need of dose to produce equal pixel value of a known object and the spatial resolution. The dose required to for a certain pixel-value was substantially equal for both devices. Spatial resolution was found to be as well substantially identical i.e. 4 - 5 lp/mm.

Conclusion
Digora PCT or Digipod has found to have substantially equivalent physical performance as the predicate device Fuji FCR 9000HQ.
Digora PCT or Digipod is shown to be able to provide images of substantially equivalent diagnostic capability with Fuji FCR 9000HQ.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Kai Laner
Director
Soredex Palodex Group Oy
Nahkelantie 160
TUUSULA FIN-04300
FINLAND

AUG 23 2013

Re: K070304
Trade/Device Name: Digora PCT or Digipod
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH, EHD, and MQB
Dated: January 25, 2007
Received: January 31, 2007

Dear Mr. Laner:

This letter corrects our substantially equivalent letter of March 27, 2007.
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Digora PCT or Digipod

Indications For Use:

The Digora PCT or Digipod imaging system is indicated for capturing, digitization and processing of extraoral, maxillofacial, cephalometric and podiatric X-ray images stored in imaging plate recording media.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyppman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070304